

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Lex P. Jansen et al.	Art Unit	: 3731
Serial No.	: 10/063,125	Examiner	: Ryan J. Severson
Filed	: March 22, 2002	Conf. No.	: 5949
Title	: MRI AND X-RAY COMPATIBLE STENT MATERIAL		

Mail Stop Appeal Brief - Patents

Commissioner for Patents

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REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Appellants respond to the Examiner's Answer as follows:

On page 2, lines 17-20 of the Examiner's Answer, the Examiner presents a new ground for rejection under 35 U.S.C. § 112, second paragraph. This rejection is also in error. Accordingly, Appellants request that this appeal be maintained and address this new ground of rejection herein, as set forth in 37 C.F.R. 41.37(c)(1)(vii).

On page 3, lines 6-18 of the Examiner's Answer, the Examiner alleges that claims 1, 3, 6-8, 26-28, and 32-38 are unclear due to the recitation of "a stent comprising a body" and "the body consisting essentially of an alloy comprising tungsten and rhenium" within the independent claims. Examiner's Answer, page 3, lines 9-11. Appellants maintain that the claims are not unclear. It is clear that the stent can include features in addition to the body (e.g., a polymer coating as recited in dependent claims 28 and 38). Consistent with this fact, the independent claims recite "a stent comprising a body." The claim then further defines what the body can be by stating that the body must "consist essentially of an alloy." The "semi-closed" limitation on what the body can be does not make the claims unclear. Accordingly, the rejection is in error and must be reversed.

On page 3, lines 18-20 of the Examiner's Answer, the Examiner states that "[f]or examination purposes, Examiner has interpreted the claims to mean that the alloy consists essentially of tungsten and rhenium." This interpretation is clearly at odds with what the claims actually recite. The independent claims recite "an alloy comprising tungsten and rhenium." The "consisting essentially of" language precedes the term "alloy" to make it clear that it is the body that "consist[s] essentially of" that alloy. The "comprising" term used immediately after the term "alloy" and preceding "tungsten and rhenium" makes it clear that the alloy can include

other elements. Only dependent claims 3 and 33 require that the alloy “consist[] essentially of tungsten and rhenium.” Other claims include other limitations on the composition of the alloy. For example, claim 1 further recites that “the tungsten is present in an amount ranging from about 75 weight percent to about 99 weight percent.” Dependent claim 6 and independent claim 32 require that “rhenium is present in an amount ranging from about 25 weight percent to about 1 weight percent.” Accordingly, Appellants request that the claims be accorded their proper scope, which is at odds with the Examiner’s erroneous interpretation.

On page 5, lines 4-5 of the Examiner’s Answer, the Examiner argues that Appellants must show evidence that the core material of Mayer could not function as a stent without the jacket. Appellants, however, are under no obligation to submit such evidence because the Examiner has not presented a *prima facie* case of obviousness. “If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.” MPEP § 2142. “To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” *Id.* There is no indication in either Gianturco or Mayer that the core material, without the presence of the casing, would have the host of properties needed for a stent. Simply being ductile or malleable is not enough. As Gianturco stresses, the material must also have “sufficient strength and stiffness to avoid the stent being displaced on the balloon during insertion and to avoid the loops 15 and 16 being forced into an overlying relation. Further, the stent has sufficient strength and stiffness to allow it to maintain its position in the passageway and to resist being dislodged after the catheter 22 has been removed and the balloon is no longer stabilizing the stent.” Gianturco, col. 4, lines 1-11. There is no indication in Mayer that the tungsten-rhenium alloy disclosed in Mayer would have these properties relating to strength and stiffness. The Examiner’s assertion using “an alloy of tungsten and rhenium” to make a stent would not result in a loss of “the physical properties of a stent disclosed by Gianturco” is completely without support. Mayer only states that the core “conforms to the shape of the case” and that “the mechanical behavior of the composite filament 18a in terms of elastic deformation in response to external stresses is, essentially, the behavior of the case 26.” Mayer, col. 6, lines 14-21. This

does not suggest that the core material has the "strength and stiffness" required for the material of Gianturco. Furthermore, this description in Mayer is not particularly directed to the specific tungsten-rhenium alloy. Accordingly, one having ordinary skill at the time of the invention, without the benefit of the Appellants' disclosure, would not have had any reason to use the core material of Mayer without the casing of Mayer to make the stent of Gianturco.

On page 5, line 20 – page 6, line 3 of the Examiner's Answer, the Examiner newly asserts that it would have been "within the level of one or ordinary skill" to add "rhenium to the tungsten material to create an alloy" because Gianturco discloses that the stent "can be made from tungsten (see column 3, line 65)." This new rationale to support the rejection is also without support. There is no disclosure of record that discloses or suggests that adding rhenium to tungsten would produce a desirable material for use as the body of a stent, as claimed. One having ordinary skill in the art at the time of invention would know that alloying additional elements would alter the material and physiological properties of an alloy. Given the infinite number of possible alloys each having different amounts of different constituents, one having ordinary skill in the art would have no guidance to find a suitable alloy of tungsten having the physical and mechanical requirements for a stent body without undue experimentation. Furthermore, there is no suggestion in Mayer that the tungsten-rhenium alloy, when used as the claimed body of the stent without the casing of Mayer, would have the physical and mechanical requirements for the stent as disclosed by Gianturco. Accordingly, the rejection using this new rationale cannot be maintained.

On page 6, lines 6-11 of the Examiner's Answer, the Examiner alleges that one having ordinary skill would select the claimed alloy to make the claimed stent "on the basis of its suitability for the intended use as a matter of obvious design choice." The Examiner, however, has never shown that the claimed alloy is known to be suitable for use as claimed: without the casing of Mayer. The only disclosure of the claimed alloy in the prior art is with the casing of Mayer. Without establishing that the claimed material is known to be suitable for its claimed use, the ruling in *In re Leshin* does not apply. The fact that the alloy is disclosed in the field of stents, but only disclosed in conjunction with the casing of Mayer, suggests that the claimed use,

which excludes the possibility of the Mayer casing, is nonobvious. Accordingly, the rejection using this new rationale cannot be maintained.

For these reasons, and the reasons stated in the Appeal Brief, Appellants submit that the final rejection should be reversed.

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Respectfully submitted,

Date: June 18, 2009

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